

**REMARKS/ARGUMENTS**

This reply is being filed in response to the Official action dated December 31, 2002 for the above-identified patent application. The period to respond is extended by petition and payment of the appropriate fee.

**Status of the claims**

Claims 23-49 are in the application.

Claims 23, 27, 28 , 30-32 and 36 have been rejected.

By way of this amendment, claims 24-27, 31-35 and 37-49 have been canceled, without prejudice, claims 23, 28 and 30 have been amended, and new claims 50-57 have been added.

Upon entry of the amendment, claims 23, 28-30, 36 and 50-57 will be pending.

**Summary of the Amendment**

Claim 23 has been amended to refer to treatment of individuals suspected of having metastatic colorectal cancer. Support for the amendment is found throughout the specification and in claim 21 as originally filed. No new matter has been added.

Claim 28 has been amended to correct its dependency.

Claim 30 has been amended to correct a typographical error.

New claims 50-57 have been added to claim specific embodiments of the invention. Support for new claims 50-57 is found throughout the specification, such as, for example, on page 17, lines 14-18.

The specification has been amended to correct a minor typographical error by replacing the erroneous designation "5-4 fluorouracil" with the correct designation "5-fluorouracil". 5-fluorouracil is well-known as a cytotoxic agent useful as a chemotherapeutic. Given the context in which it appears in the application, i.e., often grouped with other well-known cytotoxic agents, one skilled in the art would recognize the designation "5-4 fluorouracil" as an obvious typographical error and would readily understand the application to be referring to 5-fluorouracil.

No new matter has been added by these amendments.

#### **Objection to Claims 31 and 32**

Claims 31 and 32 have been objected to as being in improper dependent form for failing to further limit the subject matter of a previous claim. Claims 31 and 32 have been canceled, therefore rendering the objection moot.

#### **Withdrawal from Consideration of Claim 29 and Objection to Claim 30**

As the Examiner has noted, a provisional species election was made; Applicant hereby affirms this species election (noting that the correct designation is 5-fluorouracil, as discussed above). The Official Action indicates that claim 29 has been withdrawn from consideration and an objection has been made to claim 30 as referring to a non-elected claim (i.e., claim 29). Applicant respectfully points out that the elected species, 5-fluorouracil, reads on claim 29. Accordingly, claim 29 should not have been withdrawn from

consideration. Applicant respectfully requests that claim 29 be examined on the merits. Additionally, Applicant respectfully requests that the objection to claim 30 be withdrawn.

**Rejection under 35 U.S.C. §112, first paragraph**

Claims 23, 27, 28, 30-32, and 36 have been rejected under 35 U.S.C. §112, first paragraph, for lack of an enabling disclosure.

Applicant respectfully submits that the reasoning and evidence of record is insufficient to provide sufficient doubt of the truthfulness of Applicant's assertion of enablement. Rather, the evidence of record supports the conclusion that one skilled in the art would accept the truth of Applicant's assertion of enablement.

References Jain, Dillman and Weiner are cited in the Official Action as evidence of unpredictability with respect to antibody-based therapeutics in support of the Examiner's assertion of non-enablement. Applicant asserts, however, that these references fail to provide sufficient evidence that one skilled in the art would doubt the objective truth of Applicant's assertion that the claimed invention is enabled.

Jain and Dillman are each cited by the Examiner as pointing out problems and obstacles in developing antibody-based therapeutics. Each of these references, however, also discusses the potential and promise of antibody-based therapeutics. Additionally, Applicant urges that Weiner, which was published more recently than either Jain or Dillman, addresses many of the concerns suggested by Jain and Dillman and puts in proper context the issues raised in those references.

Weiner provides strong evidence that those having ordinary skill in the art would accept Applicant's assertion of enablement. For example, the last sentence of the full paragraph on the right column of page 41 refers to

the premature and unwarranted conclusion that antibody-based therapeutics do not show sufficient promise to be considered cutting-edge and valuable

In the paragraph bridging pages 41 and 42, and the paragraph on page 42 that follows, Weiner provides additional evidence that those skilled in the art would accept Applicant's assertion that the claimed invention is enabled. Weiner also discusses the use of drug immuno-conjugates, such as those used in the claimed invention, as a "feasible" strategy for treating cancer. See Weiner at page 48. Additionally, the summary on page 49 refers to a number of examples of clinical uses of antibodies in cancer therapy, thus demonstrating the promising nature of the approach.

A significant issue raised by the Examiner in citing Weiner concerned the specificity of an antibody-based therapeutic. As noted above, the claims have been amended to refer to methods of treating an individual suspected of suffering from metastatic colorectal cancer. As discussed in the specification, the ST receptors which are being targeted are not normally expressed outside of the intestine/colon. Further, as pointed out in the specification, the interior of the intestine/colon is tightly walled off from the inside of the body and vice versa. Thus, the compositions may be administered such that they will not interact with normal colon tissue that expresses the receptor, but will bind with cells outside the intestinal tract that are derived from the intestinal tract, such as metastasized colorectal cells. See pages 10-11 of the specification. Therefore, the concern regarding specificity outlined by the Examiner has been addressed by the amendment.

When all of the evidence of record is considered in its totality, one skilled in the art would conclude that the instant application as amended is in compliance with the requirements of the first paragraph of § 112. In view of all of the evidence, one skilled in the art would conclude that the claimed invention is enabled.

Applicant respectfully requests that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

#### **Discussion of the Rejections for Obviousness-type Double Patenting**

Without commenting on the appropriateness of the obviousness-type double patenting rejections in view of claims of issued patents commonly owned by the assignee of the present application, Applicant proposes to file a Terminal Disclaimer under 37 CFR § 1.321(c) upon the withdrawal of the remaining rejections, if deemed appropriate in view of the allowed claims.

#### **Information Disclosure Statement**

Applicant notes that the information disclosure statement submitted May 15, 2001 was considered in part; however, the Examiner has requested additional copies of references that were previously cited by or submitted to the PTO. Applicant is in the process of obtaining copies of the requested references and proposes to submit them shortly.

#### **Conclusion**

Applicant believes that the foregoing constitutes a complete and full response to the Office Action of record. Accordingly, an early and favorable reconsideration of the


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**PATENT**

rejections and an allowance of all of pending claims 23, 28-30, 36 and 50-57 are requested respectfully.

Respectfully submitted,

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